

Message Text

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PAGE 01 STATE 135023
ORIGIN HEW-06

INFO OCT-01 EUR-12 ISO-00 OES-07 AGR-10 EB-07 COME-00
/043 R

DRAFTED BY DHEW/FDA: JRWEINROTH, M.D.:CCK
APPROVED BY OES/APT/BMP: WJWALSH, III
DHEW/PHS/OASH/OIH: RFISCHER
EUR/CE:KAKURZE(INFO)
EUR/WE:JFDOBBINS(INFO)

-----110058Z 030350 /72

P 102205Z JUN 77
FM SECSTATE WASHDC
TO AMCONSUL MUNICH PRIORITY
AMEMBASSY PARIS PRIORITY
INFO AMEMBASSY BONN PRIORITY

UNCLAS STATE 135023

E.O. 11652: N/A

TAGS: OGEN, ETRD, EIND, TBIO, GW, FR

SUBJECT: FDA ADVISORY - RECALL OF IMPLANTABLE DEMAND
TYPE PACEMAKERS (RECALL T-069/072-7)

1. FDA ADVISES OF THE FOLLOWING DEVICE RECALL:

PRODUCTS INVOLVED:

T-069-7: MICRO 7, MODEL DU 700, DEMAND UNIPOLAR PACEMAKERS,
INDIVIDUAL UNIT SERIAL NUMBERS IDENTIFIED WITHIN
THE SERIES RANGE FROM S1288 THRU S1734.

T-070-7: MICRO 7, MODEL DB800, DEMAND BIPOLAR PACEMAKERS
INDIVIDUAL UNIT SERIAL NUMBERS IDENTIFIED WITHIN
THE SERIES RANGE FROM S1288 THRU S1734.

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T-071-7: MICRO 12, MODELS DU-300 AND DU 301 DEMAND UNIPOLAR
PACEMAKERS, INDIVIDUAL PACER SERIAL NUMBERS ID-
ENTIFIED WITHIN THE SERIES RANGE FROM SA121 THRU
SA772.

T-072-7: MICRO 12, MODELS DB-400 AND DB-401 DEMAND BI-

POLAR PACEMAKERS, INDIVIDUAL PACER SERIAL NUMBERS IDENTIFIED WITHIN THE SERIES RANGE FROM SA121 THRU A772.

MICRO 7 AND MICRO 12 PACEMAKERS,(DEMAND TYPE PULSE GENERATORS.) POWERED BY HERMETICALLY SEALED LITHIUM IOIDE CELL.

PRODUCT IDENTIFICATION:

MICRO 7 AND MICRO 12 PACEMAKERS, MICRO 7 INVOLVED MODELS DU-700 AND DB-400 AND DB-401. THE DU MODELS ARE DEMAND UNIPOLAR; THE DB MODELS ARE DEMAND BIPOLAR. EACH PACER UNIT HAS A UNIQUE SERIAL NUMBER. FOR MICRO 7 SERIAL NO.'S INVOLVED ARE WITH THE RANGE OF S 1288 THRU 1734; FOR MICRO 12, SERIAL S INVOLVED ARE WITHIN THE RANGE OF S A121 THRU A772, NOT ALL THE SERIAL NO. S WITHIN EITHER RANGE ARE INVOLVED IN RECALL.

MANUFACTURING/RECALLING FIRM:

AMERICAN TECHNOLOGY, INC., 19749 BAHAMA ST., NORTHRIDGE, CALIF., 91324, PHONE (213) 882-8770, IS THE MFR OF THE PACERS AND THE RECALLING FIRM. THE FIRM WHICH MFRD THE FAULTY CAPACITORS USED IN THE PACERS IS NCI, 5900 AUSTRALIAN AVE., WEST PALM BEACH, FLA., 33407, PHONE (305) 842-3201.

2. REASON FOR RECALL:

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RECALLED PACERS CONTAIN DEFECTIVE CAPACITORS. THE FAILURE MODE IS MANIFESTED BY A LEAKAGE IN THE CAPACITOR CAUSING AN ACCELERATED DEPLETION OF THE BATTERY. A RATE DECREASE OF APPROXIMATELY 3 BEATS PER MINUTE MAY BE USED AS AN INDICATOR OF PREMATURE FAILURE. TEN PREMATURE EXPLANTS HAVE BEEN REQUIRED TO DATE.

3. POSTS ARE REQUESTED TO CONTACT FOREIGN CONSIGNEES TO DETERMINE IF THEY HAVE BEEN ADVISED BY FIRM OR RECALL AND PROCEDURES TO BE FOLLOWED. ANY QUESTIONS CONSIGNEES MAY HAVE REGARDING RECALL SHOULD BE DIRECTED TO RECALLING FIRM.

4. CONSIGNEES AS FOLLOWS:

MR. WALTER KOGLEK
8081 MAMMENDORF BEI MUNCHEN
BACHSTRASSE 13

MUNICH, WEST GERMANY

MEDICOTH ELECTRONICS
98 RUE BARRAULT
75013 PARIS, FRANCE

BOTH CONSIGNEES BELIEVED TO HAVE RECEIVED MICRO 7 MODELS
ONLY. VANCE

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Message Attributes

Automatic Decaptioning: X
Capture Date: 01-Jan-1994 12:00:00 am
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: MEDICAL EQUIPMENT, RECALLS
Control Number: n/a
Copy: SINGLE
Sent Date: 10-Jun-1977 12:00:00 am
Decaption Date: 01-Jan-1960 12:00:00 am
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01-Jan-1960 12:00:00 am
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1977STATE135023
Document Source: CORE
Document Unique ID: 00
Drafter: JRWEINROTH, M.D.:CCK
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Expiration:
Film Number: D770208-0645
Format: TEL
From: STATE
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1977/newtext/t19770667/aaaachcj.tel
Line Count: 124
Litigation Code IDs:
Litigation Codes:
Litigation History:
Locator: TEXT ON-LINE, ON MICROFILM
Message ID: 916ee57e-c288-dd11-92da-001cc4696bcc
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Original Previous Classification: n/a
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Review Exemptions: n/a
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TAGS: OGEN, ETRD, EIND, TBIO, GE, FR, FDA
To: MUNICH PARIS
Type: TE
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Review Markings:
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